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November 02, 2004

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APPLICATION NUMBER: ***60/529,100***
FILING DATE: ***December 15, 2003***

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19587 U.S.PTO
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19281 U.S.PTO

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)		
Given Nam (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Adrian	Shulman	Herzliya, Israel

☐ *Additional Inventors are being named on the ^ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

METHOD AND APPARATUS FOR ULTRASOUND EMBRYO TRANSFER

CORRESPONDENCE ADDRESS

Direct all correspondence to:
☒ Customer Number 27130 *Type Customer Number here*
OR

Place Customer Number Bar Code Label here

☒ Firm or Individual Name	Eitan, Pearl, Latzer & Cohen Zedek, LLP.				
Address	10 Rockefeller Plaza				
Address	Suite 1001				
City	New York	State	New York	ZIP	10020
Country	USA	Telephone	212-632-3480	Fax	212-632-3489

ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 19 ☐ CD(s), Number
☒ Drawing(s) *Number of Sheets* 10
☐ Application Data Sheet. See 37 CFR 1.76 ☒ Other (specify) postcard

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☒ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
☒ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 05-0649
☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): 80

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.
☒ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

Date 15 / Dec / 2003

SIGNATURE

TYPED or PRINTED NAME Guy Yonay

TELEPHONE 212-632-3480

REGISTRATION NO. *(if appropriate)* 52,388

Docket Number:

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Confidential

USET MEDICAL LTD.

Business Plan

DRAFT

October 2003

Table of Contents

1. Executive Summary

USET Medical Ltd. was established In 2003 by Adrian Shulman, MD, Michal Devir, MD and Gershon Goldenberg.

The initial objective of the company is to develop a unique method for a real-time sonography guidance of intra-uterine surgical procedures. A dispossable cost effective device, will enable the use of existing high resolution real-time ultrasound equipment to visualize the targeted organ (mainly the uterus), allowing a surgeon to perform the procedure more safely and efficiently. The proposed device represents a significant break-through of the exsisting medical procedure in the field of intra uterine procedures.

One of the main objectives of USET Medical is that the proposed method will be recognized as a standard and routine way of performing imaging monitoring of any intra-uterine surgery interventions both for diagnostic and treatment purposes.

Currently the only competition to the proposed method are the existing procedures. Their main disadvantage is that they are being performed by "blind" technique based on the surgeon's experience and "feel" (intuition) through manual manipulation of surgical instrument over the uterus walls.

USET Medical intends to develop an innovate solution to this problem - a new ultrasound guidance accessory tool that will be unique in four main areas: a) it is effective and easy to use, b) it is safe, c) it is highly controlled and d) it utilizes a low cost DISPOSABLE device.

The main customers to this product are medical institutions, Fertility clinics and and gynecological clinics who perfomed uterine activities all over the world.

The market potential is very high. The potential market for **USET ™** in the field of ART alone is estimated at USD 200M a year . Other potencial markets such as IUD , CVS and Imaging are sharply growing markets and estimated in more than 1 bilion $ per year. The market share potencial of USET in the field of ART only is estimated at 5-10% of the total market in the end of second year of sales - representing sales of $10-20M . Sales for

other application and markets are estimated to contribute at least the same revenue, if not bigger.

USET Medical is seeking to raise an investment of $1 Million to support R&D, commence clinical trials, enhance intellectual property, conduct marketing and business development activities in the US and Europe,. This financing round will fund USET's activities towards product commercialization in Europe and in the USA , at which time the company's valuation is expected to escalate sharply.

2. Company Overview

USET Medical Ltd. was established in 2003 by Adrian Shulman, MD, Michal Devir, MD and Gershon Goldenberg.

Adrian Shulman, MD is a senior physician at the IVF Unit of the Obstetric and Gynecology Department In SHEBA Medical Center and holds a teaching position at Sakler Medical school at Tel-Aviv University. Dr Shulman is a well known expert in the field of human fertility, and had published more that 80 scientific papers .

Michal Devir, MD business experience includes position as Chief Executive Officer of Medical Electronics Systems (MES), a medical device company in the field of human male fertility, and management positions in several medical device and pharmaceutical companies, such as Teva Ltd, Medinol Ltd, IMT ltd. Dr. Devir has a MD degree and has graduated a Business Management Program.

Gershon Goldenberg is the co-founder of Beating Heart Ltd, a company that provides engineering and clinical development services to medical devices companies. Gershon has a B.Sc. in Electronic Engineering and graduated a Business Administration program. His professional experience includes co-founding of MTRE - Medical Thermo Regulation Equipment Ltd. and working as CTO and a project manager of the engineering group at Aran Ltd and Microvue Ltd.

The initial goal was to develop a method that will enable the physician to perform an embryo-transfer procedure under ultrasonography guidance. The proposed device will in fact provide a unique method of real-time sonography guidance for all intra-uterine surgical procedures. A simple and low cost disposable device serves as a speculum and will enable the use of high resolution real-time ultrasound visualization of the targeted organ, allowing a surgeon to perform the procedure safely and efficiently. Since no risk is involved in the implementation and use of this new concept, the company's founders strongly believe that the use of real-time trans-vaginal ultrasound guidance will eventually become a standard way of performing uterine procedures.

The founders of the company also believe that the proposed device will serve as a platform and a starting point for additional products to be evolve in the future, as the company will gain in size and reputation.

The company is privately owned.

3. Market Overview:

Intra-uterine procedures (other than endoscopies) are being performed today by traditional "blind" technique based on the surgeon's experience and expertese to "feel" through manual manipulation of surgical instrument over the uterus walls .

Among common procedures in that area are :

a) ART (assisted reproducstive technologies) procedures such as Embryo transfer during in-vitro fertilization (IVF) & Intra Uterine Insemination (IUI)
b) Insertion or removal of an intra-uterine contraceptive device
c) Removal of an endometrial polyp
d) Endometrial tissue biopsy
e) Hydrography and Tubal visualization
f) Chorionic Villi Sampling (CVS)

3.1- Assisted repduction technologies (ART) - Embryotransfer & Intrauterine insemination

Approximately 15% of all couples are faced with fertility problems and this number is growing each year. The solution for these problems may require specialized medical treatments, such as intra uterine insemination (IUI), In-Vitro Fertilization (IVF), other female infertility treatments, and male infertility treatments.
Women participating in an IVF program are stimulated to produce large quantities of oocytes (eggs; ova), usually about 8-12 oocytes per stimulatory cycle. After in vitro fertilization a portion of the embryos returned to the woman after 3-5 days (Embry-transfer). The remaining embryos are stored frozen for future implantation attempts.
Clinics compete on pregnancy success rates and quality. Embryo transfer (ET) is one of the major factors of treatment success. It is widely accepted today, that Ultrasonic guided ebryotransfer should be the golden standard of Embryo transfer. Technical issues related to the unavailability of "US transducer holder", are the main reason why Ultrasonographic guided ET is not commonly used.

This is a relatively young market which was started only on late 70' when first IVF cycle was performed, but it is growing very rapidly. The total market for human reproductive technologies reached $6.9 billion in 2001 in USA only. The global market is about twice than the US market. It is expected to rise at an average annual growth rate of 10.1% to $11 billion in2006 in the USA. The success rates of these ART procedures are relativly low

(aiming 30%), resulting multiple cycles per patient at a cost range of $4,000-10,000 per cycle .

Today, there are approximately 1,500 IVF centers worldwide, with more than half in the United States and Europe, which perform about 500,000 IVF cycles annually.

3.2 insertion & removal of intra-uterine contraceptive device

The Intra Uterine contraceptive device (IUD) is the world's most widely used method of reversible birthcontrol for women. The IUD is an object that is placed inside the uterus (womb) by a physician, usually at his clinic. The number of Intra Uterine procedures (IUI) is estimated around 2-3.5 Million annually.

Currently the insertion procedure is being performed by "blind" technique based on the surgeon's experience and "feel" (intuition) through manual manipulation of surgical instrument over the uterus walls.

The most common complication occuring during the insertion of the IUD is uterus perfuration. The incidence of intrauterine device perforation is 0.87 per 1000 insertions. An intrauterine device (IUD) may perforate through the uterine wall into the pelvic or abdominal cavity or into adjacent organs. The accepted treatment for displaced IUDs is surgical removal because of the putative risk of adhesion formation or of damage to the intestine or urinary bladder.

3.3 Removal of an endometrial polyp & Endometrial tissue biopsy

Endometrial biopsy is a method of sampling the endometrium, which can be done as an office procedure. It is an important diagnostic tool in the evaluation of abnormal uterine bleeding. It is used to exclude the presence of pathologic conditions, such as endometrial cancer and its precursors, especially atypical

endometrial hyperplasia. Endometrial Biopsy is lately becoming more common than D&C since it is considered to be more safer , cheaper and with lower incedance of complications than D&C. In addition, Endometrial biopsy is also more convenient and saves time for both the physician and the patient.

Endometrial biopsy is also used in the evaluation of patients with infertility to diagnose luteal phase defects. However, the focus of this article is the role of endometrial biopsy in determining the cause of abnormal uterine bleeding.

3.4 Hysterosonography, Hydrography and Tubal visualization

Hysterosonography, which is also called sonohysterography, is a new noninvasive technique that involves the slow infusion of sterile saline solution into a woman's uterus during ultrasound imaging. Hysterosonography allows the doctor to evaluate abnormal growths inside the uterus; abnormalities of the tissue lining the uterus (the endometrium); or disorders affecting deeper tissue layers. Hysterosonography does not require either radiation or contrast media, or invasive surgical procedures.
Hysterosonography is used to evaluate patients in the following groups:
peri- or postmenopausal women with unexplained vaginal bleeding
women whose endometrium appears abnormal during baseline ultrasound imaging
women with fertility problems. Infertility is sometimes related to polyps, leiomyomas (fibroids), or adhesions inside the uterus. Adhesions are areas of tissue that have grown together to form bands or membranes across the inside of the uterus.
women receiving tamoxifen therapy for breast cancer
Hysterosonography is useful as a screening test to minimize the use of more invasive diagnostic procedures, such as tissue biopsies and dilation and curettage (D&C). Hysterosonography can also be used as a follow-up after uterine surgery to evaluate its success

3.5 Chorionic Villi Sampling (CVS)

Chorionic villi sampling (CVS) has come to be regarded as a safe and effective diagnostic procedure for the diagnosis of fetal chromosome abnormalities and single gene

disordersvery early in the pregnancy. CVS involves aspiration of a small amount of placental tissue for prenatal testing. Technically it is similar to amniocentesis, but it is performed at 10-12 weeks gestation. Often the CVS procedure is chosen by parents who feel it is important to know as soon as possible that their baby will not have Down syndrome or certain other genetic disorders.

The procedure should be preformed under ultrasound monitoring to assure the fetal and the needle positioning. Using Vaginal US is not feasible due to technical problems, therfore the physicians prefer the transabdominal over the transcervical approach. USET method will enable the physician to use transcervical approach , and increase safety and decrease the risk of complecations.

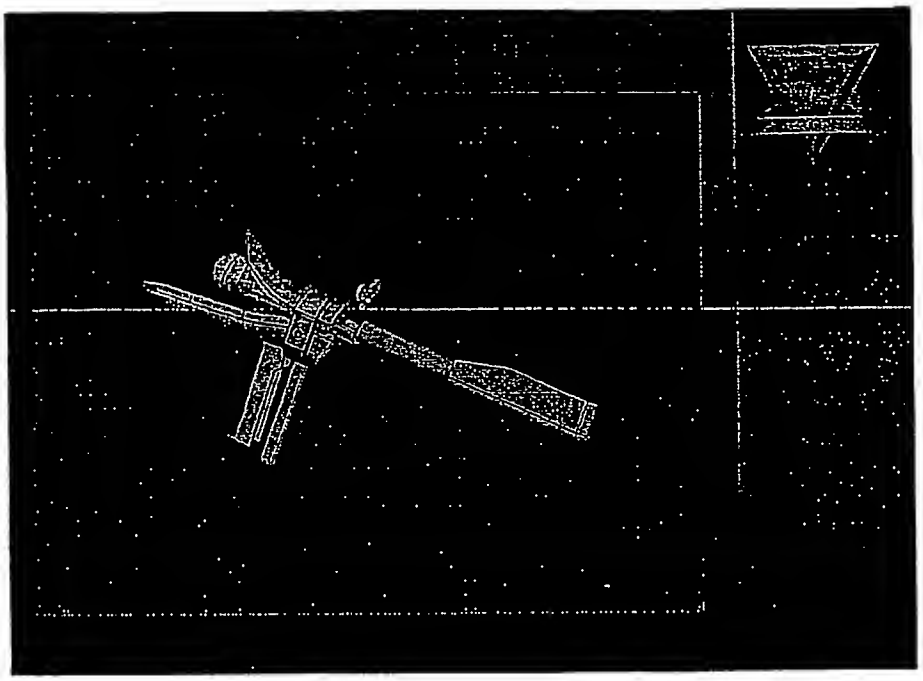
4. The Product - *USET™*

4.1 General

Uset medical will develop a proprietary method for real time sonography guidance of intra-uterine procedures.

The *USET™* is a low-cost disposable adapter device, which serves as an interface between off-the-shelf trans-vaginal ultrasound probe and the commonly used speculum instrument . The founders of the company strongly believe that the new system will eventually become a standard way of performing any intra uterine procedures, as no physician would continue to take unnecessary risks when the concept and the proposed product - the *USET™* - will be available in the market.

4.2 Product's Description



General

The vaginal speculum is a medical instrument used for assisting the gynecologist in vaginal and uterine cervix examinations. The speculum has been in use for many years in several forms, a reusable stainless steel tool is most common, disposable devices made of transparent plastic are becoming more and more popular. The device is made of two blades connected by a hinge in a design allowing a closing and opening motion similar to scissors. The speculum is inserted into the vagina when the blades are closed, then the blades open, opening the vagina allowing comfortable access. There are some gynecological procedures where the speculum is used to enable the access to the uterine cavity through the uterine cervix

Another important procedure is examination of the uterus by ultrasound. This procedure is done by introducing the ultrasound transducer manually and holding it against the vaginal inner wall. There are vaginal procedures which involve insertion of catheters into the uterus, and it's visualization by ultrasound. This procedure requires very high skills and a lot of practice by the doctor in order to achieve optimal results the transducer must be held accurately and firmly. In many cases assistance of another physician is needed.

Because of the complexity of the procedure many doctors use the abdominal approach and don't achieve the optimal result for the patient.

The U-SET speculum offers a new approach to solving many of the described above difficulties. The new device is equipped with a set of versatile adapters allowing positive attachment of ultrasound transducers, optical fibers for illumination as well as monitoring. The suggested device is also equipped with a built in illumination capability based on LED's.

The Device

The device is comprised of a stationary part and a moving part. The parts are connected by a hinge, which allows opening, by rotation to an angle of 30 degrees. Insertion of the device is done while the device is closed after placing it, by pressing the two handles the device is opened to the required size. The next step is stabilizing the speculum blades by using a specially designed hinge connecting between the two parts of the device. In order to allow attachment of the transducer to each of the device parts separately with minimum impairing of the cavity visualization. The device comprises of four parts: In any form of attaching the transducer to the speculum one blade is used for attaching the transducer while the other remains free. The adapter will be one integral part of the device blade. All parts are made of transparent and disposable plastic.

Head Adapter

There are several ultrasound transducers on the market they differ by the shape of the head, length of the neck and the handle. However the basic shape of all common products is similar. The attachment of the transducer to the speculum is based on spring loaded members which automatically adjust to all varies neck forms known on the market. Attachment of the transducer to the adapter is done by pressing the spring-loaded members until it is firmly attached. After attaching the transducer to the adapter, by moving a small button, the transducer can be firmly attached to the device in order to avoid movement during work. The adapter will be an integral part of one of the blades;

the stationary and/or the moving blade. It is possible to position the transducer head in the required position in the vagina the transducer can be slide to the required depth moving up and down or right and left movements. Placement of the transducer in the adapter allows vertical and horizontal scanning by rotating the transducer around its axis. The speculum is delivered unassembled. It is assembled by attaching the transducer to the required blade first and then attachment of the negative part.

Visual apparatus with external monitor

After placing the speculum in the vagina the duct is partially blocked by the transducers neck. The visuallity under these circumstances is very limited. Insertion of catheters or other instruments into the uterus is very problematic and inconvenient. An optical fiber 8 mm. In diameter is inserted via a special connector built on the blade beside the transducer adapter. The fiber bundle is designed in a way which allows transmitting real time video threw the middle portion of the bundle and transmitting illumination into the vagina by the outer fiber optics bundle layer. The amount of light required for activating a CCD camera is very low and the illumination is based on white LED illumination. The camera is placed in the monitor while an optical apparatus connect between the optical fibers the camera and the LED. Similar devices are used in a variety of endoscopic procedures. The advantage of this device is its ability to focus on the cervical uterus. The monitor is based on a 4" screen and a simple CCD. The vision apparatus is placed next to the doctor in a way he can keep constant eye contact with the procedure activity. Placement of the monitor is done easily because of its small size. The optical apparatus is basic and cheep including the optical fibers. The vision apparatus including the optical fiber head will be reusable.

4.3 Advantages

The benefits of using ***USET*** ™ become evident almost immediately with the inherent advatages being as follows:

- Success rates (pregnancies) of ART treatments will be increased – eliminating the need for repeated expensive & complicated treatments.
- Treatment and diagnosis of uterine problems are being preformed in effective and controlled way as compared with the current traditional "blind" alternative.
- Image guidance contributes greatly to physician's confidence and patient safety.
- Treatment can be performed in ambulatory conditions by any gynecologist with a basic expertise in ultrasound
- Complications may be reduced to a minimum, resulting in lower overall costs of surgical treatment
- Use of the device is simple and straightforward - it requires no special training and the procedure is performed exactly the same way as before.

5. Business & Revenue Models

5.1 Business Model

USET Medical estimates that it can generate initial revenues by selling its devices to health care institutions, hospitals and private practices. The Company's business model will follow two principle revenue channels which will be pursued concurrently:

Sales partnerships with Strategic Partners - Strategic partners will provide a ready made network for sales with coverage of all major markets. As a result, transfer prices will be much lower than the transfer price to an independent distributor. Based on current agreements, such as Medinol-Boston Scientific, USET is estimating approximately 40-25% of the market price of the device for any partnership agreements.

Distribution agreements with independent channels – These bodies will provide pure product distribution and sales. As such, USET will be required to allocate more funding to support marketing and sales initiatives involving these bodies. Subsequently, the Company will benefit from higher transfer price and better revenue returns when completing sales through these channels (40-50%).

While precedence will be given to Strategic partners that can supply USET with value added marketing, R&D and distribution services, the Company will consider independent distributors that possess a proven track record and a wide market reach. Initial product revenues will be realized through USET sales channels in Europe.

5.2 Revenue Model

USET predicts that European implants will commence in Q9 and will rise steadily in the years to follow. With a standard price of roughly $50, USET expects to reach penetration rates of 1%, 5%, 10% and 15% in the first four years after initial commercialization. **Given these figures, USET estimates that it will generate revenues that exceed $20 Million by 2009.**

The initial target will be the ART market with a special focus on Embryo-transfer procedures. As soon as the clinical claim of increased success rate of the IVF treatment is approved - a significant market share could be obtained within a short time. The IUI market will be the second target, and will follow the same clinical claims of the Embryo-transfer market.

Other applications will be identified following the success of the ART markets.

It is estimated that it will be possible to start marketing during the second half of year 2, and to intiate sales at the beginning of third year of company's activity (Q9). We believe that a market share of 3% (Embry-transfer only) is a feasible by the end of third year, and 15% two years later (conditioned on clinical resualts). This reflect sales of $0.75- 3.75M respectively in the Embryotransfer market only.
Sales of the IUI market will follow the ET market . IUI market share is expected to be 1% in the end of year 4, and up to 10% two years later - $1.75M-17.5M.

6. Marketing Strategy

The founders of the USET Medical bring into the company a valuble eqauntance as well as expirience of the ART world-wide device marketing.
The potential market to this product is substantially large and consists of all the medical institutions, hospital surgery wards and gynecological clinics, to be estimated at more than tens of tousands all over the world .

USET is aimed at five worldwide target markets :

1. ART market (IVF & IUI, and Hydrography and Tubal visualization)
2. General Gynecological clinics (IUD)
3. **Pregnancy clinics (Chorionic Villi Sampling (CVS)**
4. Hospital's surgery wards (Endometrial tissue biopsy & Removal of an endometrial polyp)
5. Sonography and imaging clinics (Hydrography and Tubal visualization)

USET Medical will approach each of its market with a program desingned to tailur marketing messages to specific group of potencial custumers. USET Medical will focus its marketing efforts initially at the European market (rather than at the U.S. market) because the regulatory environment for medical equipment is more lenient in Europe. However, in parallel, USET Medical will begin to develop the scientific data and regulatory documentation required for entering the US market as well.

7. Potential Competition

USET Medical believes that its technology provides answers to the market needs of all of the markets it attemps to penetrate. Currently the only competition to USET method are the existing procedures .

Based on the following facts:

a) The *USET* ™ will be well and widely covered under patents in many stretagic areas all over the world
b) USET has no intention to compete with any of the companies that produce Probes or other ultrasound accessories

the company still have to take into consideration the posibility that new competitors will soon identify the atractivness of this profitable business and will try to penetrate the market with a similar product for the same purpose. Another way to compete the new produt is by finding a better solution or improving the image quality of the abdomenal ultrasound scanning, or the visualization qualities of the vaginal device.

8. Intellectual Property

USet Medical is hoping to gain a strong portfolio of registrated patents that will provide the company with a significant advantages over potencial competition and will support the intelectual infrastructure for USET technology for many years.

It is the intention of USET medical to retain the services of a leading intellectual property firm.

9. Regulatory Affairs

USET technology demands that the company consider carefully the regulatory issues that it might be facing. Regulatory matters will determine to a considerable extent how the company proceeds with its research efforts, and will also have a considerable effect on how and where the company's marketing efforts are directed. It is the intention of the company to engage a regulatory consultants with expertise in the area of medical devices From a regulatory perspective, USET Medical can operate in two arenas: Europe (CE) and the United States (FDA), Marketing approval in Europe essentially requires only that the equipment be shown to be electrically and mechanically safe, irrespective of the application. In the USA, however, the situation is more complex, but it is likely that USET will be classified as low-risk device.

. The following regulatory approvals are listed as action items:

ISO 9001- The company should be certified prior to intiation of sales. Activities towards ISO certification are scheduled to begin on the second year of activity.

CE Mark – The product should be cleared for marketing by the EU according to the directive 93/42/EEC in European Countries.

FDA – Activities towards the FDA approval for the production, marketing and selling of the USET will start as soon as beta tests are completed. We assume that the product will be cleared by 510K. Final pathway of approval will be obtained following regulatory consultancy.

10. Mile Stones

1. Establishing of the company, incl office, man power, lab facilities – Q1
2. Submission of patent application –Q1
3. Prototype – Q2
4. Feasibility tests – Q3
5. Beta tests – Q4
6. Initiation of Multi centers clinical studies - Q5
7. Regulatory standards (CE, ISO) – Q6
8. Manufactured first batch –Q7
9. Initiation of sales – Q8
10. Balanced P&L -

11. Financial Plan

Claims:

1. A method substantially as described hereinabove.

2. A method substantially as illustrated in any of the drawings.

3. Apparatus substantially as described hereinabove.

4. Apparatus substantially as illustrated in any of the drawings.